

Front

STRIVO

(Levosulpiride)

TABLET

سٹرایوو

COMPOSITION:**STRIVO Tablet 25 mg:**

Each tablet contains:

Levosulpiride 25 mg.

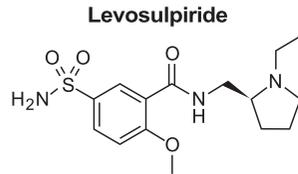
Product Specs.: Wnsfeild Specs.**STRIVO Tablet 50 mg:**

Each tablet contains:

Levosulpiride 50 mg.

Product Specs.: Wnsfeild Specs.**DESCRIPTION:**

Levosulpiride is a typical antipsychotic and a prokinetic agent of the benzamide class.[1] It is a selective antagonist of the dopamine D2 receptors[2] on both central and peripheral nervous systems. Chemically, it is the (S)-(-)-enantiomer of sulpiride (1)-N-[[[(S)-1-Etyl-2-pyrrolidinyl]methyl]-5-sulfamoyl-oanisamide.

**Pharmacodynamics:**

Levosulpiride is a substituted benzamide derivative and a selective dopamine D2 antagonist with antipsychotic and antidepressant activity. Biochemical, pharmacological and clinical data obtained with the two isomers of sulpiride, indicate that the antidopaminergic activity, both at central and local levels, is due to levo- rotatory enantiomer. It acts as an Antiemetic agent and Neuroleptic agent.

Pharmacokinetic properties:

When levosulpiride is administered orally at a dose of 50 mg, the peak plasma concentration is reached in 3 hours, in an average of 94.183 ng/ml. The 1/2 of elimination calculated after administration of 50 mg iv of levosulpiride is 4.305 hours. The elimination of the medicine occurs mainly via the urine.

INDICATIONS:

- Short-term treatment of dyspeptic syndrome (anorexia, bloating, a feeling of epigastric tenderness, postprandial headache, heartburn, belching, diarrhoea, constipation) from delayed gastric emptying related to organic factors (diabetic gastroparesis, cancer, etc.) and / or functional factors (visceral somatisation in anxious subjects -depressants) in patients who failed to respond to other therapy.
- Symptomatic short-term treatment of nausea and vomiting (induced by anticancer drugs) after failure of first-line therapy.
- Symptomatic short-term treatment of dizziness, tinnitus, hearing loss and nausea associated with Meniere's syndrome

DOSAGE & ADMINISTRATION:

Adults: According to medical prescription: 1 tablet 3 times a day before meals.

Elderly: In the treatment of elderly patients, the dosage should be decided by the physician, which must carefully evaluate a possible reduction of the dosages above mentioned.

METHOD OF ADMINISTRATION:

Oral use only: Not recommended for use in children & adolescence as there is no data available

CONTRAINDICATIONS:

- Hypersensitivity to the active substance or to any of the excipients
- Levosulpiride should not be used in epilepsy, manic states, in the manic phase of manic depressive psychosis.
- Levosulpiride is contraindicated in patients with pheochromocytoma, because it can cause a hypertensive crisis probably due to the release of catecholamines from the tumor.

Back

- Levosulpiride should not be used in subjects who are already carriers of a malignant mastopathy.
- Levosulpiride is contraindicated in pregnancy and during the breastfeeding period

Special warnings and precautions for use:

- In randomized clinical trials versus placebo performed in a population of patients with dementia treated with some atypical antipsychotics, an increase of about three times of the cerebrovascular events risk was observed. The mechanism for this increased risk is not known. An increased risk for other antipsychotics or other patient populations cannot be ruled out. Levosulpiride should be used with caution in patients with risk factors for stroke.
- A complex symptoms disorder, potentially fatal, called Neuroleptic Malignant Syndrome has been reported with use of neuroleptics (in general in the course of treatment with antipsychotic drugs). Clinical manifestations of this syndrome are hyperpyrexia, muscle rigidity, akinesia, vegetative disorders (irregular pulse and blood pressure, sweating, tachycardia, arrhythmias), altered state of consciousness that may progress to stupor and coma. The treatment of Neuroleptic Malignant Syndrome consists of immediate discontinuation of the antipsychotic medicines and other not essential medicines and setting of an intensive symptomatic treatment (care must be taken in reducing hyperthermia and in correcting dehydration). In case the resumption of the treatment with antipsychotics is held to be essential, the patient should be carefully monitored. Concomitant therapy with other neuroleptics must be avoided.
- The effects of levosulpiride on gastrointestinal motility may be antagonized by anticholinergic drugs, narcotics and analgesics.
- Levosulpiride should not be used when the stimulation of gastrointestinal motility can be detrimental, for example in the presence of gastrointestinal bleeding, mechanical obstructions or perforations.
- Levosulpiride should be used with caution in patients with cardiovascular disease or with a family history of QT prolongation.
- There have been reports of venous thromboembolism (VTE) with antipsychotic medicines use. Since patients treated with antipsychotics often present with acquired risk factors for VTE, these factors need to be identified before and during treatment with levosulpiride, in order to take appropriate preventive measures.
- Simultaneous intake of alcohol must be avoided.

Effects on ability to drive and use machines:

High doses of levosulpiride may cause drowsiness, numbness, or dyskinesias, therefore they should be advised to avoid driving and to be engaged in activities where a full alertness is required for their possible hazard.

Pregnancy & Lactation:

There are no adequate and well-controlled studies on pregnant women and during the breastfeeding. Patients should be advised of the need to inform their doctor in case of current or planned pregnancy during treatment with levosulpiride. Do not use in pregnancy, possible pregnancy and during the breastfeeding period. Neonates exposed to conventional or atypical antipsychotics included levosulpiride during the third trimester of pregnancy are at risk for side effects including extrapyramidal symptoms or withdrawal symptoms that may vary by severity and duration following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, and feeding disorder. Therefore, new-borns should be carefully monitored.

DRUG INTERACTIONS:

- Concomitant administration of neuroleptics with medicines that prolong the QT interval, increases the risk of cardiac arrhythmias.
- Levosulpiride should not be administered concomitantly with medicines that cause electrolyte disturbances.

ADVERSE REACTIONS:

Rare: QT prolongation, Ventricular arrhythmias such as torsades de pointes, Ventricular tachycardia, Ventricular fibrillation, Cardiac arrest

Very Rare: Somnolence, Parkinsonism, Dyskinesia, Tremor, Dystonia, Neuroleptic Malignant Syndrome, Sudden death

Frequency Unknown: Amenorrhoea, Gynaecomastia, Galactorrhoea, Changes in libido. Thromboembolism (including cases of pulmonary embolism and deep venous thrombosis). Neonatal withdrawal syndrome, extrapyramidal symptoms. Hyperprolactinaemia.

INSTRUCTIONS:

- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

STRIVO Tablet 25 mg : Pack of 2 x 10 tablets.

STRIVO Tablet 50 mg : Pack of 2 x 10 tablets.

Manufactured by:
WnsFeild Pharmaceuticals.
Plot # 122, Block A, Phase V, Industrial Estate, Hattar, Pakistan.

FOR FURTHER INFORMATIONS PLEASE CONTACT:



Marketed by:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔